DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food & Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

Polymedco, Inc.
c/o Ms. Helen Landicho
Vice President, Regulatory Affairs
510 Furnace Dock Rd.
Cortland Manor, NY 10567

Re: k100550
Trade Name: Poly-Chem 90 Direct HDL-Cholesterol, Direct LDL-Cholesterol, Cholesterol and Triglycerides tests
Regulation Number: 21 CFR §862.1475
Regulation Name: Lipoprotein test system
Regulatory Class: Class I, meets limitations per 21 CFR 862.9(c)(4)
Product Codes: LBS, MRR, CHH, CDT
Dated: September 14, 2010
Received: September 15, 2010

SEP 28 2010

Dear Ms. Landicho:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

SEP 2 8 2010

510(k) Number (if known):

Device Name: Poly-Chem 90 Direct HDL-Cholesterol, Direct LDL-Cholesterol, Cholesterol, and Triglycerides tests

Indications For Use:

The Poly-Chem 90 Direct HDL-Cholesterol test system is an in vitro diagnostic procedure intended to measure high density lipoproteins quantitatively in human serum on the Poly-Chem 90 analyzer. HDL Cholesterol results are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis and various other liver and renal diseases, and for the assessment for the risk of developing cardiovascular disease.

The Poly-Chem 90 Direct LDL-Cholesterol test system is an in vitro diagnostic procedure intended to measure low density lipoprotens quantitatively in human serum on the Poly-Chem 90 analyzer. LDL Cholesterol results are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis and various other liver and renal diseases, and for the assessment for the risk of developing cardiovascular disease.

The Poly-Chem 90 Cholesterol test system is an in vitro diagnostic procedure intended to measure cholesterol quantitatively in human serum on the Poly-Chem 90 analyzer. Cholesterol measurements are used in the diagnosis and treatment of lipid disorders, lipoprotein metabolism disorders and atherosclerosis.

The Poly-Chem 90 Triglycerides test system is an in vitro diagnostic procedure intended to measure triglyceride quantitatively in human serum on the Poly-Chem 90 analyzer. Triglycerides measurements are used in the diagnosis and treatment of disease involving lipid metabolism and various endocrine disorders e.g. diabetes mellitus, nephrosis and liver obstruction.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K100550